



#114
RIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)

Kenneth C. CUNDY et al.)

Application No.: 09/974,768)

Filed: October 9, 2001)

For: BILE-ACID CONJUGATES FOR)
PROVIDING SUSTAINED)
SYSTEMIC CONCENTRATIONS)
OF DRUGS)

Group Art Unit: 1616

Examiner: Barbara P. Badio

Confirmation No.: 6895

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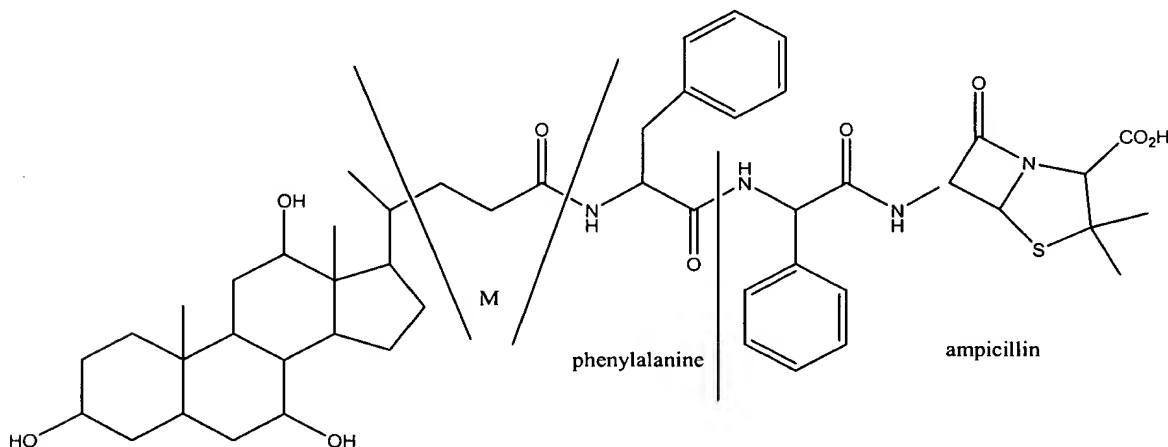
RESPONSE TO OFFICE COMMUNICATION

Assistant Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In complete response to the Office Communication of July 21, 2003, Applicants submit the following response.

In order to comply with the requirements of 37 C.F.R. § 1.143, Applicants elected in their previous response a single **disclosed** species for examination. Applicants maintain their previous election, with traverse, of the following compound of formula I:



In the elected compound of formula I, X, R¹, and R² are hydroxy; Z is a group of the formula –M-Q^{x'}; M is –CH₂CH₂C(O)–; Q^{x'} is of the structure –A^{x'}-D'; A^{x'} is derived from an α -amino acid; and D' is a drug (*as disclosed on page 82, lines 13-20*). Alpha amino acids are taught on page 33, line 18 – page 34, line 2 and on page 35, lines 1-7). On page 35, line 6, phenylalanine is specifically disclosed as a suitable α -amino acid and phenylalanine is illustrated as a suitable α -amino acid in Figure 4. Suitable drugs D' are taught on page 35, line 23 – page 37, line 11. Ampicillin is specifically disclosed as a suitable drug D' on page 36, line 15.

Since all component substituents/pieces of the elected compound of formula I (as illustrated above) are specifically disclosed in the specification, Applicants respectfully submit that the elected compound is in fact disclosed by the present application.

As recited in the MPEP, an Applicant may be required under 35 U.S.C. 121 to elect a single disclosed species for examination. The MPEP states that while it is preferred that species are identified as the species of figures 1, 2, and 3 or the species of examples I, II, and III, “[i]n *the absence of distinct figures or examples* to identify the species, the mechanical means, the particular material, or *other distinguishing characteristics of the species* should be stated for each species identified.” (MPEP 809.02(a), emphasis added).

Therefore, Applicants respectfully submit that it is not required that the elected species be illustrated as a figure or exemplified in an example or that the compound be disclosed as a complete entity at a particular location within the application. It is only required that the distinguishing characteristics of the species be stated and disclosed. Applicants respectfully submit that the present specification does, in fact, disclose all of the components of the elected compound of formula I, as set forth above. Applicants also respectfully submit that the present specification further discloses a representative synthesis of the elected compound of formula I. Accordingly, even though the elected compound is not exemplified in a particular Example or illustrated in a Figure, the compound of formula I as elected is disclosed by the present application.

Applicants further note that the specification of the present application states that [t]he following examples illustrate how the synthesis of GABA analog conjugates could be conducted in order to prepare compounds of formula (I). It is contemplated that *other drugs* may be used in place of a GABA analog with

similar synthetic schemes. The syntheses described below are illustrated in Figures 4 – 8. While *GABA is not included within the scope of this invention*, these examples are *illustrative* of how other drugs could be readily coupled to a bile acid in an analogous manner.

Page 90, lines 4-10, emphasis added. Accordingly, it is inappropriate for the Examiner to refuse to accept Applicants' elected compound of formula I and examine the claims in light of that election.

As set forth in the Response filed on June 6, 2003, it is believed that claims 1, 3, 4, 6, 8 – 10, 12, 13, 15, 17, 18, 20, and 23 are readable upon the elected species as defined above. Applicants have no intention of abandoning any non-elected subject matter and expressly reserve the right to file one or more continuation and/or divisional applications directed to the non-elected subject matter.

The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By Mel. M. Hayworth
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Dated: August 21, 2003



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Kenneth C. CUNDY et al.

Group Art Unit: 1616

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Title: BILE-ACID CONJUGATES FOR PROVIDING SUSTAINED SYSTEMIC CONCENTRATIONS OF DRUGS

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AMENDMENT/REPLY TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a reply for the above-identified patent application.

☐ A Petition for Extension of Time is also enclosed.

☐ Terminal Disclaimer(s) and the ☐ \$55.00 (2814) ☐ \$110.00 (1814) fee per Disclaimer due under 37 C.F.R. § 1.20(d) are also enclosed.

☐ Also enclosed is/are _____

☐ Small entity status is hereby claimed.

☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the
☐ \$375.00 (2801) ☐ \$750.00 (1801) fee due under 37 C.F.R. § 1.17(e).

☐ Applicant(s) requests that any previously unentered after final amendments not be entered.
Continued examination is requested based on the enclosed documents identified above.

☐ Applicant(s) previously submitted _____

_____ on _____
for which continued examination is requested.

☐ Applicant(s) requests suspension of action by the Office until at least _____,
which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R.
§ 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.

☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.

- ☒ No additional claim fee is required.
- ☐ An additional claim fee is required, and is calculated as shown below.

AMENDED CLAIMS					
	No. of Claims	Highest No. of Claims Previously Paid For	Extra Claims	Rate	Additional Fee
Total Claims		MINUS =	0	x \$18.00 (1202) =	\$ 0.00
Independent Claims		MINUS =	0	x \$84.00 (1201) =	\$ 0.00
If Amendment adds multiple dependent claims, add \$280.00 (1203)					
Total Claim Amendment Fee					\$ 0.00
<input type="checkbox"/> Small Entity Status claimed - subtract 50% of Total Claim Amendment Fee					\$ 0.00
TOTAL ADDITIONAL CLAIM FEE DUE FOR THIS AMENDMENT					\$ 0.00

- ☐ A total fee in the amount of _____ is enclosed.
- ☐ Charge _____ to Deposit Account No. 02-4800.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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Date: August 21, 2003

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